



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/658,261      | 09/08/2000  | Jay N. Cohn          | 102258.288          | 3689             |

25270 7590 12/05/2001

EDWARD D GRIEFF  
HALE & DORR LLP  
1455 PENNSYLVANIA AVE, NW  
WASHINGTON, DC 20004

EXAMINER

HENLEY III, RAYMOND J

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/658,261

Applicant(s)  
Jay N. Cohn, et al.

Examiner  
Ray Henley

Art Unit  
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

Art Unit: 1614

**CLAIMS 1-41 ARE PRESENTED FOR EXAMINATION**

---

Applicants' Information Disclosure Statements filed September 8, 2000, October 27, 2000, February 6, 2001, April 24, 2001 and November 18, 2001 have been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449, the cited references have been considered.

***Claim Rejection - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohn (U.S. Patent No. 4,868,179).

Cohn teaches a method of reducing mortality associated with chronic congestive heart failure in a patient with impaired cardiac function and concomitant reduced exercise tolerance with comprises the administration of between about 75 and 300 mg. of hydralazine, per day, and between about 40 and about 160 mg. of isosorbide dinitrate, per day. See the abstract. The patentee further teaches that the patient is additionally placed on a regimen of another cardiovascular-treating drug such as conventional diuretic therapy to manage edema and

Art Unit: 1614

depending on the diuretic employed, potassium compounds or foods high in potassium content may be employed. The patentee highlights diuretics such as chlorthiazide, hydrochlorothiazide, ethacrynic acid, furosemide, spironolactone and triamterene. See column 2, line 62 - column 3, line 18. It is also highlighted that digoxin is a conventional treatment for congestive heart failure (column 3, line 68 - column 4, line 1).

The differences between the above and applicants' claimed subject matter lies in that the patentees fail to highlight:

- (1) isosorbide mononitrate or other hydralazine compounds;
- (2) a black patient population;
- (3) additional treatment with other agents useful for treating a cardiovascular disease (e.g., present claim 29); and
- (4) a kit containing the active ingredients.

However, to the skilled artisan, applicant's claimed subject matter would have been obvious because:

(1-2) Given that isosorbide dinitrate and hydralazine compounds are taught to be effective, it would have logically flowed that compounds structurally/therapeutically similar would also be effective which would have motivated the skilled artisan to select such compounds from those known. Also, the patentee teaches patients in general and thus would have included all race populations.

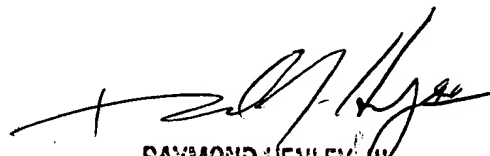
Art Unit: 1614

(3) As noted above, the patentee teaches patients in general and thus would have included those suffering from other disorders, including cardiovascular disorders other than congestive heart failure, and taking the appropriate medication for treating such other disorders.

(4) The selection of a specific packaging means would have been a matter well within the purview of the skilled artisan.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.



RAYMOND HENLEY, JR.  
PRIMARY EXAMINER  
GROUP 1000

Henley; rjh  
November 30, 2001